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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,993	07/22/2003	Svetlana A. Sukhishvili	101995.013901	8177

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,993	SUKHISHVILI ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-31* is/are pending in the application.

4a) Of the above claim(s) *17 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16 and 18-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/22/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

In summary of the current election, applicant elected Group III and the species where the claimed process requires adjusting the pH of the film to create the first excess charge first, then creating a second excess charge opposite to the first excess charge, then contacting the film with the macromolecule solution and repeating the sequence, such that a bioactive agent is the macromolecule. The search has been expanded to also include the same process species where the macromolecule is a polymer.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure only recites separate layers of polymer and macromolecules not a blend of the two in a single layer that is present on top of a layer of the macromolecule, as claimed here.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps required to build the multilayered system where the macromolecule is present in a polymer layer and composes the layer beneath this blended layer.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim15 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The phrase "at least through electrostatic interaction" in claim15 is a relative term which renders the claim indefinite. The term phrase "at least through electrostatic interaction" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically it is unclear what would be “greater” than electrostatic interaction. This recitation could refer to the relative strength of the bonds, additional types of bonds, or some other meaning all together.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries set forth by Graham V. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15, 19, 21-28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sukhishvili et al. (Journal of the American Chemical Society 2000 122:9550-9551) in view of Dubas et al. (Journal of the American Chemical Society 2001 123:5368-5369).

Sukhishvili et al. teach a process of reversibly producing a layered polymer film, such that the layers can be selectively removed (see title and column 1 paragraph 1 lines 7-11; instant claim 15). Additionally, Sukhishvili et al. also teach that these films have applications in medicine and pharmaceuticals, such as in drug release (see page 9550 column 1 paragraph 1 lines 12-14 and page 9551 column 1 paragraph 1 line-column 1; instant claim 15) The layered structure is taught to be built from the sequential addition of poly-acid or poly-base layer to a substrate; thus like acid and base, both of these types of polymers can be modulated between an electrostaticly charged and uncharged state (see column 1 paragraph 2 lines 2-3; instant claims 15 and 28). The process of introducing charge within the layered system prompts electrostatic repulsion where the amount of charge introduced determines the amount of material released for the layered system (see figure 2; instant claim 15). In addition, Sukhishvili et al. also teach that the deconstruction of the layers is controllable such that a graded removal of portions of the layered system can occur (see figure 2). The full

dissolution of the layers occurs at such a sharp pH that values just below this pH allow for selective removal of a fraction of the layers, without complete destruction (see figure 2 upper panel). Further Sukhishvili et al. also teach that polymer systems other than those exemplified could also be used in this process and suggest synthetic polymeric nucleotides (bioactive macromolecules) in particular (see page 9550 column 1 paragraph 2 lines 7-13; instant claim 20). Sukhishvili et al. do not specifically teach electrostaticly bonded multi-layer systems.

Dubas et al. teach a polyelectrolyte multilayer system that is connected by both hydrogen and electrostatic bonding (see page 5369 column 1 paragraph 3). In particular, they teach a pair of polyelectrolytes bound in this way, namely poly(acrylic acid) and poly(diallyldimethylammonium) (see page 5369 column 1 paragraph 3; instant claims 21-27 and 30). Dubas et al. also teach that this multilayer system is subject to a similar dissolution process as those taught by Sukhishvili et al., triggered by a change in pH. Unlike Sukhishvili et al., except at extreme levels a change in pH itself is not sufficient to completely dissolve the layered system (see page 5369 column 1 paragraph 3). Since these layers have two types of bonds holding them together, their dissolution can be more controlled. Due to this increased level of control, it would have been obvious to one of ordinary skill in the art at the time of the invention to the use the polymer pair taught by Dubas et al. as the erasable polyelectrolyte system and method taught by Sukhishvili et al. Therefore claims 15, 19, 21-28, and 30 are obvious over Sukhisvili et al. and Dubas et al.

Claims 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sukhishvili et al. in view of Dubas et al. as applied to claims 15, 19, 21-28, and 30 above, and as evidenced by the Hampton Research MSDS.

Sukhishvili et al. in view of Dubas et al. make obvious the process of claim 15 (see ***Claim Rejections - 35 USC § 103*** for claims 15, 21-28, and 30). This modified reference does not explicitly discuss the bioactivity of the components used in the polyelectrolyte multilayers. The Hampton Research MSDS for Polyacrylic acid indicates that this compound was known to be an eye irritant, upon contact. Therefore this compound can be classified as a bioactive since it was known to have physiological activity. Thus claims 15 and 20 are obvious over Sukhishvili et al. in view of Dubas et al. and as evidenced by the Hampton Research MSDS.

Claims 15, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sukhishvili et al. in view of Dubas et al. as applied to claims 15, 19, 21-28, and 30 above, and further in view of Hiller et al (USPGPub No. 2003/0215626).

Sukhishvili et al. in view of Dubas et al. make obvious the process of claim 15 (see ***Claim Rejections - 35 USC § 103*** for claims 15, 21-28, and 30). This modified reference does not teach the addition of macromolecule after a portion has been released, nor the repetition of macromolecule release and addition to the layered system.

Hiller et al. teach a very similar process and set of polymers (e.g. poly acrylic acid) to construct a multilayered polyelectrolyte film (see Hiller et al. paragraph 29 lines

9-10 and 30; Sukhishvili et al. page 9550 column 1 paragraph 2 lines 2-5). Both Hiller et al. and Sukhishvili et al. teach a change in layer behavior that is controlled by pH (producing a change in the ionization state of polymer in the layers), removal of layers in the case of Sukhishvili et al. and porosity in the case of Hiller et al. (see Sukhishvili et al. page 9550 column 2 paragraph 3; Hiller et al paragraph 34 lines 1-8). Further Hiller et al. teach that the pH induced porosity can be cycled (film made porous, then non-porous, repeatedly) within the multi-layered structures (see paragraph 47 lines 1-7; instant claim 16). Since it is possible to cycle the ionization within such multilayered structures, it would have been obvious to one of ordinary skill in the art at the time of the invention to practice the process of instant claim 15 and then cycle the ionization (or charge balance) in the layer, by altering the pH, such that the layered structure could be reversibly built again. In addition, since common charge prompted the repulsion responsible for the layer removal, it would have been obvious at the time of the invention to one of ordinary skill in the art to induce an opposite charge in the remaining structure to rebuild the layers. Furthermore, according to MPEP 2144.04, the duplication of parts, or steps in the case of a process, does not impart any patentable significance unless some expected result is produced. [see In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (Claims at issue were directed to a water-tight masonry structure wherein a water seal of flexible material fills the joints which form between adjacent pours of concrete. The claimed water seal has a “web” which lies in the joint, and a plurality of “ribs” projecting outwardly from each side of the web into one of the adjacent concrete slabs. The prior art disclosed a flexible water stop for preventing passage of

water between masses of concrete in the shape of a plus sign (+). Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.).] Therefore claims 15, 16, and 18 are obvious over Sukhishvili et al. in view of Dubas et al., and Hiller et al.

Response to Arguments

Applicants' arguments, filed September 22, 2008, have been fully considered but they are not deemed to be persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615